Remarks/Arguments

Claims 1, 3-10 are rejected under 35 U.S.C 102(b) as being anticipated by Gravener et al., U.S. Pat. No. 5,360,417. Claim 2 is rejected under 35 U.S.C. 103 as unpatentable over Gravener in view of Mollenauer et al., U.S. Pat. No. 5,514,109. Claim 10 has been amended. Claims 1-9 are discussed below.

Claims 1-5: Claim 1 is an independent claim, with claims 2-5 depending therefrom. Claim 1 provides, emphasis added:

> A surgical valve having an axis extending between a proximal and a distal end, comprising:
>
> a housing including a proximal housing portion and **a distal housing portion** cooperating with the proximal housing portion to define a gel cavity;
>
> a seal material disposed in the gel cavity, the seal material including a gel having non-compressible characteristics;
>
> a proximal guide tube extending axially proximally from the proximal housing portion;
>
> the proximal guide tube facilitating insertion of a surgical instrument into the seal material;
>
> **a distal guide tube extending axially distally from the distal housing portion**, **the distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal**.

MPEP § 2131 provides:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). . . . "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)."

As noted above, claim 1 recites both a "distal housing structure" (please see Figure 6, 76a, in the Application) and a "distal guide tube" (please see Figure 6, 85a, in the Application) "extending axially distally from the distal housing portion" and "facilitating retrograde insertion of the surgical instrument into the surgical seal." The Office action points to the device in Gravener, identifying a "distal housing portion (18)" and a "distal guide tube (18) extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument (44) into the surgical seal (see Figure 7)" . . . . (Office action, page 2).

Applicants respectfully disagree. First, figure 7 in Gravener does not depict the retrograde insertion of a surgical instrument into a distal guide tube. Figure 7 is a continuation of figure 6, in which a surgical instrument 44 is inserted into the **proximal** opening 22 of the device. See Gravener, col. 3, lines 14-19 ("FIG. 6 is a side elevational partial cut-away view illustrating the valve assembly prior to insertion of a surgical instrument; FIG. 7 is a side elevational partial cut-away view illustrating the valve assembly during insertion of a surgical instrument . . . ."); col. 5, lines 17-31 ("Referring to FIGS. 6-9, a pointed obturator is shown approaching and entering valve assembly 10 . . . . The **proximal** opening 22 is of such a diameter to sealingly engage instrument 44 during insertion and withdrawal." Emphasis added.)

Second, the distal end portion of the Gravener device includes no guide tube extending axially distally from the housing. See Gravener, col. 4, lines 32-24 ("a distal end portion 18 which is elongated and substantially cylindrical in shape. The distal end portion 18 further includes a distal edge 20 whose significance will be discussed below." As "discussed below" in Gravener, this distal end portion is folded back on itself to form a circumferential pocket into which gel can be pumped to inflate the pocket, sealing it around any instrument inserted through it.

According to Gravener, col. 4, line 56 through col. 5, line 11, emphasis added:

> "As shown in Figs. 4 and 5, the elongated substantially cylindrical distal portion 18 is folded onto itself and pulled proximally in the direction of the arrows. The distal edge 20 is affixed to the proximal wall plate 24 creating a cavity 40 by conventional techniques such as adhesives or heat sealing. Inlet port 36 is provided for injection of a gel 42, e.g., silicone, or like substance into cavity 40 while outlet port 38 provides a conduit for eliminating air from cavity 40. The gel 42 fills cavity 40 and provides

> longitudinal and radial pressure about the aperture 14 (FIG. 3) The gel 42 biases the middle portion 28 of aperture 14 closed, preventing gases and fluids from escaping through the body 12 when no instrument is present in the valve assembly 10. Similarly, the gel 42 biases the middle portion 28 of aperture 14 into fluid tight contact when an instrument is present in the aperture by longitudinally and radially providing pressure about the aperture 14 (FIG. 7). Valve assembly 10 is preferably incorporated into a cannula assembly of a trocar assembly similar to specific embodiments described herein below.
>
> Aperture 14 is typically dimensioned less than or equal to the diameter of any instrument intended for entry into the **proximal** end of the body 12."

Further, Applicants respect that to the extent Gravener's distal portion 18 is construed as a distal housing structure of the present invention, it cannot be both a housing structure and a guide tube extending therefrom.

As the device in Gravener does not, to Applicants' knowledge, contemplate retrograde insertion of instruments, nor provide for a distal guide tube to facilitate such retrograde insertion, it cannot anticipate claim 1 nor any of the claims depending therefrom. Accordingly, Applicants respectfully request that the §102 rejection of claims 1 and 3-5 be withdrawn.

Moreover, Applicants respectfully request that the §103 rejection of claim 2 be withdrawn. As noted above, Gravener fails to teach a distal guide tube extending axially distally from a distal housing structure, which facilitates retrograde insertion of an instrument. The Office action points to no teaching or suggestion in Mollenauer of such a guide tube. Accordingly, the Office action fails to make a prima facie case of obviousness.

Claims 6-9: Claim 6 is an independent claim, with claims 7-9 depending therefrom. Claim 6 provides, emphasis added:

> A surgical valve, comprising:
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> a first housing portion defining a gel cavity;
>
> **a seal material including a gel and having a node and an axial channel**;
>
> a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state; and
>
> a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state.

As noted above, claim 6 and the claims depending therefrom include a **seal material having a node** (see Fig. 6, 116, in the Application). According to the Office action, Gravener teaches "a node (32) . . . ." Applicants respectfully disagree that Gravener's structure 32 discloses a node in a seal material. According to Gravener, "the proximal end portion 16 further includes a plurality of **splines 32** attached to an inner wall 34 and preferably integrally molded as part of inner wall 34. Alternatively, splines 32 may be insert molded and may include rigid members below the surface of

inner wall 34, e.g., metallic strips or the like. The splines 32 extend in a generally longitudinal direction to assist in the insertion of an instrument into the neck portion 26 by reducing friction and drag forces associated therewith. Further, the splines 32 substantially prevent unwanted contact between the instrument and the inner wall 34 of the neck 26 that may injure or puncture the body 12." Col. 4, lines 41-53.

Applicant respectfully disagrees that Gravener's splines anticipate Applicants seal material node. Accordingly, Applicants respectfully request that the §102 rejection of claims 6-9 be withdrawn.

Based on foregoing remarks, Applicants respectfully submit that all pending claims are in condition for allowance and earnestly solicit a notice thereof. Applicants encourage the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the Application.

Sincerely

APPLIED MEDICAL RESOURCES

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